

Appl. No. 10/754,362
Amdt. dated Nov. 17, 2006
Reply to Office action of Aug. 23, 2006

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 2. This sheet, which includes Figs. 1-3, replaces the original sheet including Figs. 1-3

Attachment: Replacement Sheet

REMARKS

Claims 1-46 are presented for review. With the foregoing amendments and following comments, Applicants respectfully request reconsideration and allowance of all pending claims.

Fig. 2 is amended to more clearly identify it as an illustration of the prior art. In the paragraph beginning on page 4, line 16, the specification notes that Fig. 2 shows a graft 18 that has been attached to a vessel wall 12 “[a]s described in the background portion hereof...” As an example, the paragraph continues, the graft 18 may include a stent to drive deployment of a distal end 20 of the graft 18. The inclusion of a stent to open the graft is known, as acknowledged in the background section of the specification. Applicants note potential problems with stent-driven grafts by observing in the paragraph beginning on page 1, line 21, that “The long term integrity of the proximal seal for such stent grafts depends on the integrity of the stent and the barbs which are used.” By contrast, the paragraph beginning at page 4, line 27 of the specification describes Fig. 3 as illustrating a suturing device 30 “in accordance with one embodiment of the present invention.” The description accompanying Fig. 2 includes no such reference to the present invention, and therefore it is clear that the illustration of a graft having a stent, as shown in Fig. 2, is known technology on which the present invention improves.

Accordingly, Fig. 2 should be properly labeled as a representation of the prior art.

Turning to the Office action, the Examiner rejects claims 24-25, 36-37, and 42-43 under 35 U.S.C. 102(b) as anticipated by Frazier et al. (U.S. Published Patent Application No. 2001/00394436). Applicants traverse this ground of rejection.

Independent claim 24 as amended, as well as claims 25-43 dependent directly or indirectly thereon, recites a method of fixing an implantable device to a wall of a body cavity, wherein the implantable device is provided in a radially contracted configuration but is deployable to a radially expanded configuration. The method includes advancing a plurality of resilient delivery members into the implantable device disposed within the body cavity, with the implantable device in the radially contracted configuration. The delivery members are radially expanded until distal ends of the delivery members engage and drive the implantable device from the radially contracted configuration to the radially expanded configuration, thereby to urge the implantable device against the wall of the body cavity. Finally, a fixation component is

advanced from within each of the delivery members by inserting a pusher distally into each of the delivery members until a portion of each fixation component pierces the implantable device and the wall of the body cavity. It is not seen that Frazier et al. disclose or suggest the method specified in claims 24-43.

In fact, Frazier et al. disclose an endoluminal anchor for securing a graft to a vessel. The anchor may be positioned using an anastomosis catheter 126 that includes a plurality of anchor supports 62. Each anchor support 62 includes a proximal section 70, a distal section 72, and a hinge 74 joining the proximal and distal sections. An anchor 92 is disposed in a distal section 72 of each support 62 and is carried by an introducer 96 having a sharpened tip 100. A deployment wire is pulled proximally to lodge the anchor 92 into the intended treatment site. Significantly, if one considers the anchor 92 to be responsive to the claimed fixation component, then it is evident that Frazier et al. fail to disclose or suggest inserting a pusher distally to deploy the anchor.

Because Frazier et al. fail to disclose or suggest each of the elements of claims 24, it follows that claims 24-25, 36-37, and 42-43 are not anticipated thereby. In addition, Frazier et al. fail to disclose or suggest that it would be desirable or even possible to deploy a fixation component using a pusher, and hence a *prima facie* case of obviousness has not been established.

The Office action further rejects claims 24-25, 27-34, 42-44, and 46 under 35 U.S.C. 102(b) as anticipated by Miller (WO 02/17797). Applicants traverse this ground of rejection.

Independent claim 24, as well as claims 25-43 dependent directly or indirectly thereon, recites a method of fixing an implantable device to a wall of a body cavity, wherein the implantable device is provided in a radially contracted configuration but is deployable to a radially expanded configuration. The method includes advancing a plurality of resilient delivery members into the implantable device disposed within the body cavity, with the implantable device in the radially contracted configuration. The delivery members are radially expanded until distal ends of the delivery members engage and drive the implantable device from the radially contracted configuration to the radially expanded configuration, thereby to urge the implantable device against the wall of the body cavity. Finally, a fixation component is advanced from within each of the delivery members by inserting a pusher distally into each of

the delivery members until a portion of each fixation component pierces the implantable device and the wall of the body cavity. It is not seen that Miller disclose or suggest the method specified in claims 24-43.

More specifically, Miller fails to disclose or suggest delivery members that engage and drive an implantable device from a radially contracted configuration to a radially expanded configuration. Instead, Miller teaches an endovascular grafting apparatus including a stent 230 for driving the graft to the radially expanded configuration. Miller, therefore, fails to disclose or suggest expansion of the graft using the delivery members, specified in claim 24, and the anticipation rejection of claims 24-25, 27-34, and 42-43 must be withdrawn.

Independent claim 44, as well as claims 45-46 dependent directly or indirectly thereon, recites a fixation system for use in a wall of a blood vessel having an aneurysm. The system includes a graft sized to extend across the aneurysm and having no outwardly biasing structure associated therewith. The system includes an array of delivery tubes advancable through a center lumen of the graft, wherein each delivery member has a distal end formed with a blunt profile and the array of tubes is movable between a radially contracted position and a deployment position in which the distal ends of the delivery tubes expand radially to urge the graft against the wall. It is not seen that Miller discloses or suggests such apparatus.

More specifically, Miller fails to disclose or suggest a fixation system including a graft having no outwardly biasing structure associated therewith. Instead, Miller teaches a graft 225 having an integrated stent 230 which biases the graft to the radially expanded configuration. Consequently, Miller fails to disclose or suggest each element of claim 44, and the anticipation rejection of claims 44 and 46 must be withdrawn.

The Office action further rejects claims 1-3, 10-14, 22-23, 26, and 45 under 35 U.S.C. 103(a) as obvious over Miller. Applicants traverse this ground of rejection.

Independent claim 1, as well as claims 2-23 dependent directly thereon, recites a fixation system for use in a body cavity including an implantable device having no outwardly biasing structure associated therewith. As noted above, Miller teaches the use of a graft having a stent, which outwardly biases the graft, and therefore fails to disclose or suggest this element of claim 1. Accordingly, the obviousness rejection of claims 1-3, 10-14, and 22-23 must be withdrawn.

CONCLUSION

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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Respectfully submitted,

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